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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,830	04/02/2004	Donald R. Huene	6200.250DIV	8861
7590	03/28/2005			
Joseph W. Berenato, III Liniak, Berenato & White, LLC Suite 240 6550 Rock Spring Drive Bethesda, MD 20817			EXAMINER MILLER, CHERYL L	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

87N

Office Action Summary	Application No. 10/815,830	Applicant(s) HUENE, DONALD R.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 16, 17 and 19-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 16, 17, and 19-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment #1</u> |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-6, 16, and 17 have been considered but are moot in view of the new ground(s) of rejection.

The previous rejection has been withdrawn due to the new rejection of claims 1, 6, and 16, and the current office action is a non-final rejection.

Drawings

The drawings were received on February 11, 2005. These drawings are approved.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "said adaptor first end bore" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "first end bore" to recite --second end bore--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3738

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 16, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Huene et al. (US 5,376,121, cited in previous office action). Referring to claim 1, Huene discloses a prosthesis (fig.1-3) comprising a humeral component (14+138 or just 138 alone) having a pair of arms (134+146 and 126+144; or just 146 and 144) spaced by distance one (fig.3) and having axially aligned bores (148, 150), an ulnar component (10) having an end with a bore (36) and adapted to pivotably engage the humeral component (fig.3), and an adaptor (12+50) having a first end (50) pivotably connected to the ulnar component (10) and a second end (right side of 12) pivotably connected to the humeral component (14+138; or 138 alone), the adaptor (12+50) second end having a width less than distance one and a bore (76) and the adaptor first end (50) having a pair of arms (56, 58) spaced apart by distance one (fig.3).

Referring to claim 16, Huene discloses a joint (fig.1-3) comprising a first component (14+138) having a proximal end (118) for mounting in a bone and a second end having a pair of spaced apart arms (134+146 and 126+144), a second component (10) having a distal end (20) adapted to mount in a bone and a proximal end having a bore (36), and a connector (12+50) having a first end (right side of 12) having a bore (76) pivotably mounted between the first component arms (134+146 and 126+144) and a second end (50) having a pair of spaced apart arms (56, 58), the second component (10) proximal end being pivotably mounted between the connector spaced arms (56, 58).

Art Unit: 3738

Referring to claims 6, 23, and 24, Huene discloses a pin (176) connecting the humeral component (14+138) to the adaptor (12+50) second end, and a pin (104) connecting the ulnar component (10) to the adaptor first end (50).

Referring to claim 25 and 26, Huene discloses each of the humeral arms (134+146 and 126+144) to have a bore with a diameter, the bores of both arms being coaxially aligned (fig.3).

Claims 1, 6, 16, 23-27, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Wack et al. (US 6,699,290 B1, cited in previous office action). See figure 19 and respective portions of the specification.

Referring to claim 1, Wack discloses a prosthesis (fig.19) comprising a humeral component (430) having a pair of arms (436) spaced by distance one and having axially aligned bores (437), an ulnar component (410+420) having an end (near 420) with a bore (transversing 424 in the direction of the pin) and adapted to pivotably engage the humeral component (430), and an adaptor (440) having a first end (left side of 440 in fig.19) pivotably connected to the ulnar component (410+420) and a second end (right side of 440 in fig.19) pivotably connected to the humeral component (430), the adaptor second end (right side) having a width less than distance one (due to cut-outs 441a, 442a) and a bore (445) and the adaptor first end (left side) having a pair of arms (flanges on 440) spaced apart by distance one (see attachment #1).

Referring to claim 16, Wack discloses a joint (fig.19) comprising a first component (430) having a proximal end (433) for mounting in a bone and a second end having a pair of spaced apart arms (436), a second component (410+420) having a distal end (412) adapted to mount in a bone and a proximal end having a bore (transverse to 424), and a connector (440) having a first

Art Unit: 3738

end (right side of 440 in fig.19) having a bore (445) pivotably mounted between the first component arms (436) and a second end (left side of 440 in fig.19) having a pair of spaced apart arms (flanges on 440), the second component proximal end being pivotably mounted between the connector spaced arms (fig.19).

Referring to claims 6, 23, and 24, Wack discloses a pin (450 or 460) connecting the humeral component (430) to the adaptor (440) second end (fig.19), and a pin (450 or 460) connecting the ulnar component (410+420) to the adaptor (440) first end.

Referring to claim 25 and 26, Wack discloses each of the humeral arms (436) to have a bore (437) with a diameter, the bores of both arms being coaxially aligned (fig.19).

Referring to claims 27 and 32, Wack discloses the first component (430), second component (410+420), and adaptor/connector (440) to be formed of a metal, such as steel, titanium, or alloys thereof (bearings may be metal, col.7, lines 26-29; ulnar component may be metal, col.8, lines 54-56; humeral may be metal, col.9, lines 16-18).

Claims 1, 6, 16, 17, 19, 23-26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lendinara (US 2,362,383). See figures 7, 8 and respective portions of the specification.

Referring to claim 1, Lendinara discloses a prosthesis (fig.7, 8) comprising a humeral component (bottom female terminal link in figs) having a pair of arms spaced by distance one and having axially aligned bores (see fig.7), an ulnar component (top male terminal link) having an end with a bore (see fig.8) and adapted to pivotably engage the humeral component, and an adaptor (either one of the intermediate links shown in fig.7; take for instance, the top

Art Unit: 3738

intermediate link) having a first end (female end of the intermediate link) pivotably connected to the ulnar component (top terminal link) and a second end (bottom male end of intermediate link) pivotably connected to the humeral component (is adapted to link with the bottom female terminal link), the adaptor second end having a width less than distance one and a bore and the adaptor first end having a pair of arms spaced apart by distance one.

Referring to claim 16, Lendinara discloses a joint (fig.7, 8) comprising a first component (bottom female terminal link seen in fig.7) having a proximal end for mounting in a bone and a second end having a pair of spaced apart arms, a second component (top male terminal link) having a distal end adapted to mount in a bone and a proximal end having a bore, and a connector (either of the intermediate links seen in fig.7; or both intermediate links may be considered an adaptor/connector) having a first end (male end) having a bore pivotably mounted between the first component arms (see fig.7) and a second end (female end) having a pair of spaced apart arms, the second component proximal end being pivotably mounted between the connector spaced arms (fig.7).

Referring to claims 6, 23, and 24, Lendinara discloses a pin (23) connecting the humeral component (female terminal link) to the adaptor (intermediate link) second end, and a pin (23) connecting the ulnar component (top male terminal link) to the adaptor (intermediate link/links first end.

Referring to claim 25 and 26, Lendinara discloses each of the humeral arms to have a bore with a diameter, the bores of both arms being coaxially aligned (fig.7, 8).

Referring to claims 19 and 28, Lendinara discloses a first U-shaped spacer (other intermediate link) mounted between the humeral component spaced arms (see fig.7).

Referring to claim 17, Lendinara discloses a prosthetic kit comprising a first component (bottom female terminal link in fig.7) having a first end (bottom peg end) and a second end (top end) having spaced apart arms by a first distance, a second component (top male terminal link in fig.7) having a first end (top end) and a second end (bottom end) comprising a bore with a width less than the first distance (fig.7), and a U-shaped spacer (bottom intermediate link) for pivotally connecting the first component (bottom terminal link) directly to the second component (top terminal link), the spacer (bottom intermediate link) having a first end (bottom male end of the intermediate link) receivably between the first component spaced arms and a second end (top female end of the intermediate link) having first and second spaced legs for receiving the second component second end therebetween (is capable of doing so), and an adaptor (top intermediate link) for pivotally connecting the first component (bottom terminal link) second end indirectly to the second component (top terminal link) second end, the adaptor (top intermediate link) having a first end (bottom male portion of intermediate link) having a width less than the first distance and a second end (top female portion of intermediate link) having first and second arms spaced apart by the first distance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huene et al. (US 5,376,121, cited in previous office action). Huene discloses a prosthetic elbow joint

Art Unit: 3738

substantially as claimed (see above and fig.3). Huene discloses a first component (14+138), second component (10) and a connector/adaptor (50+12). Although Huene discloses some of the components to be made of metals (col.3, lines 12-14), Huene does not disclose all of the components to be made of metal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make all components including the adaptor/connector, to be made of metals such as steel, titanium, or alloys thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 20-22, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lendinara (US 2,362,383). Referring to claims 21 and 30, Lendinara discloses a prosthetic comprising a first component, second component, an adapter connector, and a U-shaped spacer. Lendinara does not however comprise a second U-shaped spacer. It would have been obvious to one having ordinary skill in the art at the time the invention was made, since each of Lendinara's components are complimentary of each other, to have an additional component, since although Lendinara only shows four linked components, five linked components is a mere duplication of parts and is not patentably significant unless an unexpected result is produced. *In re Harza*, 274 F.2d 449, 104 USPQ 400 (CCPA 1955).

Referring to claims 20, 22, 27, 29, and 31-34, Lendinara discloses a joint having several linked components substantially as claimed. Lendinara's components are formed of wood instead of metals and polymers as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the components of metal or polymers,

Art Unit: 3738

since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER